REMARKS

Claim Status

Claims 1-9 and 20-30 are pending in the present application. No additional claims fee is believed to be due.

Claims 8 and 9 and 28-30 are canceled without prejudice. Claims 10-19 were previously canceled.

Claims 1 has been rewritten and the remaining claims have been amended to correspond to amended claim 1.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 USC §102(b) Over Kawashima or Kaplan

Claims 1-5 and 20-25 stand rejected under 35 USC §102(b) as being anticipated by Kawashima (US Patent 5,882,706) or Kaplan (US Patent 4,626,541). Applicants respectfully traverse these rejections. Claims 1-5 and 20-25 have been amended.

Kawashima discloses drink and other liquid fluids, but does not disclose any method of treating or preventing cold or flu. More specifically Kawashima discloses nothing with respect to methods of treating or preventing cold or flu or spraying anything into one's nasal passages. Kawashima's compositions are directed solely at making their ferrosoferric water taste better and perform better generally by taking the chlorine taste out of water. In addition, the Japanese apricot vinegar, as shown in Table 1 of Kawashima, has a pH of 1.9. Thus, Kawashima's composition and Applicants' compositions do not inherently meet the same functional limitations. The pH of the composition used in Applicants' methods is between about 3.5 to about 5.5. Kawashima's disclosed pH of 1.9 is not within that range, or even close. The pH and therefore the properties and function of the two compositions are not inherently the same. The pH does differentiate the composition used in Applicants' method from that of Kawashima. Such a low pH may well irritate nasal passages if used in Applicants' methods. The pH has been adjusted and selected for Applicants' methods to provide effective treatment without irritation. Because Kawashima discloses only a composition (a different composition) and not a method, and provides no disclosure or teaching with

respect to any reason or mechanism to administer their compositions into nasal passages, Kawashima therefore does not disclose all of the elements of the claimed invention and therefore does not anticipate the claimed invention.

Kaplan also discloses only compositions, not methods. Kaplan discloses highly stable, water soluble product that is used as an anti-tumor agent. Kaplan discloses nothing with respect to any method of treating cold or flu or admistering a compound to the nasal passages. Therefore, Kaplan does not disclose all of the elements, all of the method steps, of the present invention, and Kaplan does not anticipate the present invention.

Because neither Kawashima nor Kaplan disclose any methods of treating cold or flu, or any methods of administering material to the nasal passages, they do not contain all of the elements of Applicants' invention and do not anticipate the claimed invention. Applicants therefore respectfully request withdrawal of the rejections.

Rejection Under 35 USC §102(b) Over Yamamoto

Claims 1-5 also stand rejected under 35 USC §102(b) based upon a public use or sale of the invention based on the teachings in Yamamoto – using Yamamoto's analysis of the components of vinegar to state that vinegar exists for sale and has for a long time. Applicants respectfully traverse these rejections. Claims 1-5 have been amended. Yamamoto discloses only a means for analyzing various components of vinegar simultaneously. Yamamoto does not disclose any method of treating or preventing a cold or flu, nor does Yamamoto disclose any method for application of vinegar or anything at all to one's nasal passages. Therefore, Yamamoto does not disclose all of the method elements of Applicants' invention and thus does not anticipate Applicants' invention. Applicants therefore respectfully request withdrawal of the rejections.

Rejection Under 35 USC §103(a) Over Yamamoto in view of Li, et al.

Claims 1-5, 8-9, 20-25 and 28-30 stand rejected under 35 USC §103(a) as being unpatentable over Yamamoto in view of Li, J. et al. CN 1079259. Claims 8-9 and 28-30 have been canceled, thus obviating the rejections of those claims. Applicants therefore respectfully request withdrawal of the rejections of claims 8-9 and 28-30. Applicants traverse the rejections of claims 1-5 and 20-25.

The rejections of claims 1-5 and 20-25 are traversed for two reasons. First, Yamamoto does not establish a *prima facie* case of obviousness because it does not teach or suggest all of the claim limitations of Claims 1-5 and 20-25. Second, even if a *prima facie* case were established, the obviousness argument is overcome by the showing of unexpected results noted at page 6, lines 22-24 in the specification. At page 6, lines 22-24 Applicants note that the spray application of Applicants' combination of certain organic acids and other components, at a pH of about 3.5 to about 5.5, applied to the nasal tissues, surprisingly creates a low pH, virus-hostile environment, but does not irritate the delicate nasal passages. Therefore, the claimed invention is unobvious and the rejections should be withdrawn.

Yamamoto does not teach or suggest all of the claim limitations of Claims 1-5 and 20-25 and, therefore, does not establish a *prima facie* case of obviousness (see MPEP 2143.03). Specifically Yamamoto ONLY teaches methods for analyzing the components of vinegar simultaneously, without having to separate them first. Examiner states that Yamamoto teaches that vinegar comprises pyroglutamic acid and a "secondary" organic acid such as succinic or acetic acid. Though pyroglutamic, succinic and acetic acid are disclosed in Yamamoto, it is not accurate to say that pyroglutamic acid is the primary acid found in vinegar along with a "secondary" acid such as acetic acid. Based on the data of Yamamoto, acetic acid is by far the most plentiful acid, with only a mere trace of pyroglutamic acid found. In addition, several general and scientific dictionaries define "vinegar" as a dilute solution of acetic acid, or acetic acid with "impurities". Therefore, pyroglutamic acid would not commonly be known as a "vinegar". Thus, Yamamoto is analyzing the minor "impurity" acids of vinegar, not providing a pyroglutamic acid composition with acetic acid as a "secondary" organic acid.

Also, Yamamoto does not teach anything with respect to any health properties or methods of using vinegars. In fact, the only "non-analytical" statement in Yamamoto with respect to vinegars is that brewery vinegar is used as a seasoning. Examiner is correct that Yamamoto thus provides no teaching or suggestion whatsoever, explicit or implicit, that would lead a skilled artisan to any method of treating a cold or flu by administering vinegar in any manner.

In addition, the composition used in Applicants' methods, a primarily pyroglutamic acid composition, would not generally be described as "vinegar". If one were looking for teachings with respect to pyroglutamic acid and its uses, one would not look to art describing an HPLC method for analyzing the composition of vinegar.

Li et al. is used by Examiner to show that "edible vinegar" can be formulated into a nasal preparation and administered into the nose for treating influenza or the common cold. Again, vinegar is generally known as a dilute solution of acetic acid with very small, trace amounts of pyroglutamic acid possibly present. But in general vinegar is not primarily a pyroglutamic acid composition and thus Li et al. teaches nothing with respect to the use of pyroglutamic acid specifically. Li et al. does not disclose, in the abstract, any particular type of "edible vinegar". Thus, Li et al. teach nothing with respect to methods of using primarily pyroglutamic acid.

In summary, Yamamoto simply teaches methods for analyzing the possible minor component acids of vinegars without having to first separate out the acetic acid. Li et al. simply teaches that some "edible vinegars" can be made into nasal compositions. Neither reference teaches or suggests, implicitly or explicitly, any method of treating or prevting colds or flu by spraying liquid pyroglutamic acid-based compositions into the nasal passages. And even if a *prima facie* case had been established, the presumption of obviousness would have been overcome by the showing of unexpected results – as noted above wherein Applicants' methods use relatively low pH compositions that are effective against cold and flu viruses yet do not irritate the user's nasal passages.

Rejection Under 35 USC §103(a) Over Yamamoto in view of Li, et al. and further in view of Szentmiklosi et al.

Claims 6-7 and 26-27 stand rejected under 35 USC §103(a) as being unpatentable over Yamamoto in view of Li, et al. as applied to claims 1-5, 8-9, 20-25 and 28-30 and further in view of Szentmiklosi et al. US Patent 5,244,880.

Claims 8-9 and 28-30 have been canceled. Applicants traverse the remaining rejections. As argued above Applicants do not believe Yamamoto alone and/or in combination with Li et al. establish a *prima facie* case of obviousness. Examiner is correct that neither Yamamoto nor Li et al. teach anything with respect to mucoadhesive carbohydrate polymers.

Applicants contend that neither Yamamoto nor Li et al., alone or in combination would lead one to Applicants methods of the present invention. Simply adding general teachings of mucoadhesive polymers would not lead one of ordinary skill in the art to Applicants invention. There is no motivation whatsoever in Yamamoto to combine

vinegar with anything for any reason. Yamamoto simply developed a method for analyzing multiple components simultaneously via HPLC. Simply because Li et al. disclose a composition that can be applied to the nose and Szentmiklosi discloses mucoadhesive polymers would not lead one of ordinary skill in the art to Applicants methods of treating and preventing colds and/or flu.

In addition, Applicants disagree with Examiner's assessment that topical compositions encompass nasal compositions. Formulations are often changed, as even noted in Szentmiklosi, depending on solubility, whether they are absorbable, burn the skin, etc. See column 1, lines 30-51. Even though Carbopol 940 is disclosed by Szentmiklosi as a gelling substance, there is still no teaching, suggestion, or motivation to use the compositions of Szentmiklosi in methods of treating cold or flu by application of compositions to the nasal passages. The whole reference is directed to external skin treatments, primarily for use as antibiotics for acne.

Simply because a composition can or may be able to be used in a certain way or method, there must be some motivation or suggestion in the cited references to combine the references. In this case there is none. Szentmiklosi only discusses application of the compounds as skin antibiotics. There is no teaching or suggestion, explicit or implicit, to use the compositions in methods of treating viruses, only bacteria, and no suggestion whatsoever to use the compositions in the nose. In fact, Szentmiklosi's necessarily very specific compositions all are 40%-60% by volume isopropanol. Szenmiklosi's compositions actually teach away from Applicants invention. One of ordinary skill in the art would probably not want to put a 60% solution of isopropanol directly into one's nasal passages and onto one's nasal mucosa. One wipes skin wounds with isopropanol to kill bacteria, but does not put it into one's nose. Thus, Applicants assert first that topical skin compositions would not be the same to a skilled artisan as compositions for nasal use, and secondly, specifically in this case, that the specific compositions described by Szentmiklosi would not be suitable for application to the nasal passages and directly onto the nasal mucosa.

Thus, none of the cited references, alone or in combination teach or suggest Applicants methods, nor provide any motivation to one of ordinary skill in the art to even attempt to combine the cited references. Therefore, Applicants methods are not obvious in view of the cited references and Applicants respectfully request withdrawal of the rejections.

Conclusion

In light of the above amendments and remarks, it is requested that the Examiner reconsider and withdraw the rejections under 35 USC § 102(b) and §103(a). Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 8, 9, 28, 29, and 30 is respectfully requested.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

By Kristin Kohler

Kristin Kohler
Registration No. 41, 907
(513) 622-3371

Date:
Customer No. 27752
(Amendment-Response to Office Action.doc)
Revised 8/3/2005